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10/723,991	11/26/2003	Michael Dahlin	1039-0011-CIP	7990	
34456 - 7590 - 66222099 LARSON NEWMAN ABEL & POLANSKY, LLP 5914 WEST COURTYARD DRIVE			EXAM	EXAMINER	
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SUITE 200 AUSTIN, TX 78730		ART UNIT	PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/723 991 DAHLIN ET AL. Office Action Summary Examiner Art Unit R. David RINES 3623 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 26 November 2003. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-58 is/are pending in the application. 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-58 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s)

PTOL-326 (Rev. 08-06)

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date \_

Notice of Draftsperson's Patent Drawing Review (PTO-948)
Notice of Draftsperson's Patent Drawing Review (PTO-948)
Notice of Draftsperson's Patent Drawing Review (PTO-948)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

Notice of Informal Patent Application.

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## DETAILED ACTION

# Notice to Applicant

[1] This communication is in response to the patent application filed 26 November 2003. It is noted that this application benefits from Provisional Patent Application Serial No. 60/430,453 filed 3 December 2002. It is further noted that this application is a Continuation-In-Part (CIP) of United States Patent Application serial number 09/440,557 filed 15 November 1999. The Information Disclosure Statements filed 26 November 2003, 9 August 2004, 22 September 2005, and 1 February 2006 have been entered and considered. Claims 1-58 are pending.

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#### Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b, b) another filled in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filled in the United States before the invention by the applicant for patent, except that an international application filled under the treaty defined in section 551(a) shall have the effects for purposes of this subsection of an application filled in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the finglish language.

[2] Claims 1-4, 8-15, 17-39, 42-44, and 58 are rejected under 35 U.S.C. 102(e) as being anticipated by Mayaud (United States Patent #5,845,255).

As per claim 1, Mayaud discloses a computer-implemented method for integrating information into a medical workflow process, the method comprising: receiving data associated with a patient (Mayaud; col. 8, lines 49-63, col. 14, lines 56-67, col. 16, lines 39-67, col. 19, lines 17-33, and col. 20, lines 20-31 \*see "select patient by ID, enter conditions, enter problems, i.e., data associated with a patient); initiating a computer search of information based on the received data associated with the patient (Mayaud; Abstract, col. 8, lines 34-67, col. 13, lines 31-40, col. 15, lines 25-67 \*see "dynamic assembly of records from remote databases"); receiving search results from the computer search of information (Mayaud; col. 11, lines 1-16, col. 15, lines 8-58, and Fig. 16 \*see "receive data records from remote databases"); and integrating the search results into the medical workflow process (Mayaud; col. 11, lines 50-67, col. 12, lines 1-32, col. 15, lines 25-67, col. 19, lines 17-42 \*see display of patient specific data by function, i.e., "integrating").

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As per claim 2, Mayaud discloses a method wherein integrating the search results comprises presenting at least a portion of the search results and the data associated with the patient in a combined view (Mayaud; col. 35, lines 44-67, col. 36, lines 1-31 Figs. 6-11 \*see formulary search data incorporated into the prescribing screen, i.e., "combined view").

As per claim 3, Mayaud discloses a method wherein the combined view is displayed on a portable computational device (Mayaud; col. 7, lines 57-67).

As per claim 4, Mayaud discloses a method wherein the medical workflow process includes interface pages associated with at least one of history of present illness, medical history, review of systems, medication, physical examination, and test results (Mayaud; col. 19, lines 17-35, col. 20, lines 1-49, col. 33, lines 54-67, col. 34, lines 1-53, col. 41, lines 43-67, col. 42, lines 17-32 \*see diagnosis history, prescription history, problems and conditions, laboratory and diagnostic data).

As per claim 8, Mayaud discloses a method wherein initiating the computer search is performed asynchronously with the medical workflow process (Mayaud; col. 11, lines 1-16, col. 15, lines 8-58, and Fig. 16 \*see "receive data records from remote databases").

As per claim 9, Mayaud discloses a method further comprising: pre-fetching information associated with the search results (Mayaud; col. 11, lines 1-16, col. 25, lines 15-45).

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As per claim 10, Mayaud discloses a method further comprising: performing a second search after additional data is gathered through the workflow process (Mayaud; col. 11, linwa 1-16, col. 25, lines 15-34 \*see update button and host computer facilities remotely retrieves data as-needed, i.e., "second search").

As per claim 11, Mayaud discloses a method further comprising: sorting the search results as additional data is gathered through the workflow process (Mayaud; col. 11, linwa 1-16, col. 25, lines 15-34.

As per claim 12, Mayaud discloses a method further comprising: filtering the search results as additional data is gathered through the workflow process (Mayaud; col. 11, lines 1-16, col. 25, lines 15-34, col. 35, lines 44-67, col. 36, lines 1-31 Figs. 6-11).

As per claim 13, Mayaud discloses a method further comprising: computing at least one probable diagnosis from the data associated with the patient (Mayaud; col. 14, lines 39-55 \*see "recommendations").

As per claim 14, Mayaud discloses a method wherein the at least one probable diagnosis is an input to the computer search (Mayaud; col. 33, lines 35-67, col. 34, lines 1-26).

As per claim 15, Mayaud discloses a method further comprising: integrating the search results into a composite query result (Mayaud; col. 33, lines 35-67, col. 34, lines 1-26).

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As per claim 17, Mayaud discloses a method wherein the step of integrating comprises adding links to information on a page associated with the workflow process (Mayaud; col. 33, lines 35-67, col. 34, lines 1-26 \*see item selection, i.e., "links")

As per claim 18, Mayaud discloses a method wherein the step of integrating comprises integrating text into a page associated with the workflow process (Mayaud; col. 41, lines 43-62).

As per claim 19, Mayaud discloses a method wherein the step of integrating comprises providing a message box in the workflow process (Mayaud; col. 12, lines 18-30, col. 23, lines 19-29).

As per claim 20, Mayaud discloses a method wherein the step of integrating comprises providing a list of references on a page accessible during the workflow process (Mayaud; col. 5, lines 60-67, col. 40, lines 1-37).

As per claim 21, Mayaud discloses a method wherein the step of initiating a search comprises querying remote databases (Mayaud; Abstract, col. 8, lines 34-67, col. 13, lines 31-40, col. 15, lines 25-67 \*see "dynamic assembly of records from remote databases").

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As per claim 22, Mayaud discloses a method wherein the remote database is associated with a government disease control entity (Mayaud; col. 23, lines 7-18).

As per claim 23, Mayaud discloses a method wherein receiving data comprises gathering data from multiple input sources (Mayaud; Abstract, col. 8, lines 34-67, col. 13, lines 31-40, col. 15, lines 25-67).

As per claim 24, Mayaud discloses a method wherein the information comprises medical algorithms and step therapies (Mayaud; col. 41, lines 14-40 \*see formulary).

As per claim 25, Mayaud discloses a method wherein the search is initiated in accordance with user preferences (Mayaud; col. 12, lines 35-67).

As per claim 26, Mayaud discloses a method wherein the search is initiated in accordance with domain-specific medical knowledge (Mayaud; col. 33, lines 35-67, col. 34, lines 1-33).

As per claim 27, Mayaud discloses a method wherein the information comprises a clinical trial database (Mayaud; col. 22, lines 52-67).

As per claim 28, Mayaud discloses a method wherein the search results comprise a treatment algorithm (Mayaud; col. 41, lines 14-40 \*see formulary).

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As per claim 29, Mayaud discloses a method wherein the treatment algorithm is associated with the patient's payer (Mayaud; col. 41, lines 14-40 \*see formulary).

As per claim 30, Mayaud discloses a method wherein the information is input by different entities (Mayaud: col. 7, lines 13-20, col. 8, lines 34-67, col. 11, lines 1-28).

As per claim 31, Mayaud discloses a method wherein one or more of the entities inputting the information pay to input information (Mayaud; col. 37, lines 17-31).

As per claim 32, Mayaud discloses a method wherein the entities pay based on whether the search results include the entity's data (Mayaud; col. 37, lines 17-31).

As per claim 33, Mayaud discloses a method wherein the entities pay based on whether the search result is selected (Mayaud; col. 37, lines 17-31).

As per claim 34, Mayaud discloses a method wherein the entities pay based on whether a product associated with the entity is ordered for the patient (Mayaud; col. 37, lines 17-31).

As per claim 35, Mayaud discloses a method wherein the information is stored in more than one data store (Mayaud; col. 8, lines 34-67, col. 11, lines 1-28).

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As per claim 36, Mayaud discloses a method wherein search input parameters associated with the computer search are operationally different for differing data stores (Mayaud; col. 7, lines 30-45, col. 11, lines 1-16).

As per claim 37, Mayaud discloses a method wherein the data associated with the patient comprises data entered during the medical workflow process (Mayaud; col. 8, lines 49-63, col. 14, lines 56-67)

As per claim 38, Mayaud discloses a method wherein the data associated with the patient is received from more than one user (Mayaud; col. 7, lines 14-20).

As per claim 39, Mayaud discloses a method wherein a first user inputs the data associated with the patient and a second user observes the search results (Mayaud; col. 7, lines 14-20).

As per claim 42, Mayaud discloses a method wherein receiving data associated with the patient comprises storing information in a patient's electronic medical record (Mayaud; col. 8, lines 35-63, col. 9, lines 1-15).

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As per claim 43, Mayaud discloses a method wherein receiving data associated with the patient occurs during one medical encounter and wherein, the method further comprises displaying the search results during a subsequent medical encounter (Mayaud; col. 8, lines 35-63, col. 9, lines 1-15).

As per claim 44, Mayaud discloses a method wherein the search results comprise information about a medication associated with a patient condition and wherein the data associated with the patient comprises at least two of a patient's diagnosis, a patient's allergies, a patient's formulary, and a prescriber's prescribing history (Mayaud; col. 19, lines 17-67).

As per claim 58, Mayaud discloses a system for receiving information associated with patient medical data, the system comprising: at least one user interface for receiving patient medical data (Mayaud; col. 7, lines 30-56, col. 8, lines 49-63, col. 11, lines 1-24, col. 14, lines 56-67, col. 16, lines 39-67, col. 19, lines 17-33, and col. 20, lines 20-31 \*see "user interface devices" and "select patient by ID, enter conditions, enter problems, i.e., data associated with a patient); a database for storing records associated with the patient medical data (Mayaud; Abstract, col. 7, lines 30-45, col. 8, lines 34-67, col. 11, lines 1-24, col. 13, lines 31-40, col. 15, lines 25-67 \*see "databases" and "dynamic assembly of records from remote databases"); a server coupled to the database (Mayaud; col. 7, lines 30-45, col. 11, lines 1-40); and at least one healthcare data storage computer, the server configured to initiate a search of the at least one healthcare data storage computer based

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on the patient medical data to provide a search result (Mayaud; Abstract, col. 7, lines 30-45, col. 8, lines 34-67, col. 11, lines 1-24, col. 13, lines 31-40, col. 15, lines 25-67 \*see "databases" and "dynamic assembly of records from remote databases").

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- [3] Claims 5-7 and 45-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud in view of McIlroy et al. (United States Patent #5,583758).

Regarding claims 5-7, Mayaud discloses compiling a virtual patient record from multiple remote databases of primary source information by online interrogation of all possible primary sources of electronically recorded patient history elements and Mayaud further discloses a patient data "directory" that provides routing information to each patient's record elements as needed during different phases of medical treatment (Mayaud; col. 8, lines 34-65). While Examiner considers the noted teachings of Mayaud to be indicative of search rules directing the retrieval of relevant medical data, Mayaud fails to explicitly

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state that the "routing information" and "directory" include search logic or rules to direct searching of the remote data sources.

However, as evidenced by McIlroy et al., it is well known in the art define specific search rules and logic to direct online searching to gather information relevant to the medical treatment of a patient (McIlroy et al.; col. 9, lines 27-43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the patient data directory and associated "routing information" with search rules/logic presented in the analogous disclosure of McIlroy et al. with a reasonable expectation of success. The motivation to make the modification would have been to define logic, process, and exclusions in order to efficiently expend time and resources in assembling scientific support for treatment decisions (McIlroy et al.; col. 9, lines 27-39).

As per claim 45, Mayaud discloses a system for processing information associated with patient medical data, the system comprising: at least one user interface for receiving patient medical data (Mayaud; col. 7, lines 30-56, col. 8, lines 49-63, col. 11, lines 1-24, col. 14, lines 56-67, col. 16, lines 39-67, col. 19, lines 17-33, and col. 20, lines 20-31 \*see "user interface devices" and "select patient by ID, enter conditions, enter problems, i.e., data associated with a patient); a database storing data records associated with the patient medical data (Mayaud; Abstract, col. 7, lines 30-45, col. 8, lines 34-67, col. 11, lines 1-24, col. 13, lines 31-40, col. 15, lines 25-67 \*see "databases" and "dynamic assembly of

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records from remote databases"); a server having access to the database (Mayaud; col. 7, lines 30-45, col. 11, lines 1-40); the server configured to initiate a search resulting in a search result based on the data records stored in the database (Mayaud; Abstract, col. 7, lines 30-45, col. 8, lines 34-67, col. 11, lines 1-24, col. 13, lines 31-40, col. 15, lines 25-67 \*see "server" and "dynamic assembly of records from remote databases"); and a network interface accessible by the server, the server initiating the search and receiving the search result through the network interface (Mayaud; col. 7, lines 30-45, col. 11, lines 1-16, col. 15, lines 8-58, and Fig. 16 \*see "receive data records from remote databases").

Mayaud discloses compiling a virtual patient record from multiple remote databases of primary source information by online interrogation of all possible primary sources of electronically recorded patient history elements and Mayaud further discloses a patient data "directory" that provides routing information to each patient's record elements as needed during different phases of medical treatment (Mayaud; col. 8, lines 34-65). While Examiner considers the noted teachings of Mayaud to be indicative of search rules directing the retrieval of relevant medical data, Mayaud fails to explicitly state that the "routing information" and "directory" include search logic or rules to direct searching of the remote data sources.

However, as evidenced by McIlroy et al., it is well known in the art define specific search rules and logic to direct online searching to gather information relevant to the medical treatment of a patient (McIlroy et al.; col. 9, lines 27-43).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the patient data directory and associated "routing information" with search rules/logic presented in the analogous disclosure of McIlroy et al. with a reasonable expectation of success. The motivation to make the modification would have been to define logic, process, and exclusions in order to efficiently expend time and resources in assembling scientific support for treatment decisions (McIlroy et al.; col. 9, lines 27-39).

As per claim 46, Mayaud discloses a system wherein the at least one user interface is a wireless handheld data entry device (Mayaud; col. 7, lines 57-67).

As per claim 47, Mayaud discloses a system wherein the search result is integrated into a medical workflow accessed through the at least one user interface (Mayaud; col. 11, lines 1-25).

As per claim 48, Mayaud discloses a system further comprising: a user preference for use in initiating the search (Mayaud; col. 12, lines 35-67).

As per claim 49, Mayaud discloses a system further comprising: an algorithm for determining at least one diagnosis (Mayaud; col. 14, lines 39-55 \*system considers laboratory data a makes diagnostic recommendations, i.e., an "algorithm").

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As per claim 50, Mayaud discloses a system further comprising: a compilation of information referenced by the search (Mayaud; col. 8, lines 34-67).

As per claim 51, Mayaud discloses a system wherein the compilation of information comprises treatments (Mayaud; col. 14, lines 10-55).

As per claim 52, Mayaud discloses a system wherein the compilation of information comprises tests (Mayaud; col. 14, lines 10-55).

As per claim 53, Mayaud discloses a system wherein the compilation of information comprises a clinical trial database (Mayaud; col. 22, lines 52-67).

As per claim 54, Mayaud discloses a system wherein the compilation of information is associated with a government disease control entity (Mayaud; col. 23, lines 7-18).

As per claim 55, Mayaud discloses a system wherein the search is initiated in accordance with domain-specific medical knowledge (Mayaud; col. 33, lines 35-67, col. 34, lines 1-33).

As per claim 56, Mayaud discloses a system wherein the search result comprises a treatment algorithm (Mayaud; col. 41, lines 14-40 \*see formulary).

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As per claim 57, Mayaud discloses a system wherein the treatment algorithm is associated with a patient's payer (Mayaud; col. 41, lines 14-40 \*see formulary).

Regarding claims 46-57, the conclusion of obviousness and motivation to combine as discussed with regard to claim 45 above are applicable to claims 46-57 and are herein incorporated by reference.

[4] Claims 16, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayaud in view of Examiner's Official Notice.

As per claim 16, while Mayaud discloses retrieval of articles and references from MEDLINE (Mayaud; col. 48, lines 29-38), Mayaud fails to explicitly state that MESH terminology is utilized by the system.

However, Examiner takes Official Notice it is well known art that MEDLINE catalogs articles using the MESH terminology and further that it would have been obvious to one of ordinary skill in the art to utilize the standardized terminology with the motivation of retrieving organization-specific data to provide scientific support for medical decisions (Mayaud; col. 48, lines 10-38).

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As per claims 40 and 41, Mayaud fails to disclose patient entry of data.

However, Examiner takes Official Notice that systems configured to enable the entry and review of medical data directly by the patient are well known in the art. One would have been motivated facilitate patient data entry with the motivation of ensuring assembly of a patient record from all possible primary sources of patient medical data (Mayaud; col. 8, lines 36-45).

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Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to R. David RINES whose telephone number is (571)272-

5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Beth Boswell can be reached on 571-272-6737. The fax phone number for

the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

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800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. David RINES/

Examiner, Art Unit 3623